

### **REMARKS**

This is in response to the Final Office Action mailed February 7, 2007.

Claims 1, 8, 22 and 24 have been amended. Support for the amendments case can be found throughout the originally filed specification. No new matter has been added.

Independent claim 1 and its dependent claims 2-3, 5-21 and 28-30, independent claim 22 and its dependent claim 23, and independent claim 24 and its dependent claims 26-27 are currently pending and at issue.

### **Claim Rejections - 35 U.S.C. §103**

Claims 1-3, 5-7, 9-20, 22-24 and 26-30, have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Howard (U.S. Patent No. 4,237,118) in view of "The Milk Mustache Campaign" (<http://agcommcase.ifas.ufl.edu/mustache.html>) ("Tabbita"). Applicants respectfully traverse.

Applicants contend that Examiner has not established a *prima facie* case of obviousness as set forth in MPEP §§ 706.02(j) and 2143, because none of the cited references teach or expressly or impliedly suggest any of the limitations set forth in the present claims.

### **Independent claims 1, 22 and 24**

The Examiner rejected claim 1, 22 and 24, asserting that Howard teaches the claimed invention, but fails to teach the communicating means, which is taught by Tabbita. The Examiner concludes that it would have been obvious to a person of ordinary skill at the time of the application, to know that retailers of calcium-enriched products (such as dairy products), would promote the consumption of the products for a benefit against obesity.

Applicants disagree with the Examiner's rejection because none of the cited art teach or suggest methods for inducing the consumption of calcium-containing products or dairy for weight loss in an individual in need thereof based on promoting or communicating the benefits of calcium from the calcium containing products or dairy to directly induce weight loss, reduce weight gain, and/or increase the metabolic consumption of adipose tissue in the individual.

Amended independent claims 1, 22, and 24 are directed to methods of inducing consumption of calcium-containing products or dairy for weight loss in an individual in need thereof, by promoting or communicating to consumers suffering from obesity that in combination: (1) consuming dietary

calcium from calcium-containing products or dairy in an amount that is above suboptimal, e.g., 773 mg of calcium per day or about 57 servings of dairy per month, over a period of time, and (2) maintaining a restricted caloric diet below ad lib in a range that is about 200 kcal to about 2500 kcal per day, during that period of time, has benefits on body weight or body fat from the consumption of the dietary calcium from the calcium-containing product or dairy product, in inducing weight loss, reducing weight gain, and/or increasing the metabolic consumption of adipose tissue in the individual.

Applicants contend that the present invention is distinct from Howard and all the other cited references because none of the cited or applied references, either alone or in combination, disclose, teach or suggest the methods of independent claims 1, 22, and 24.

For example, Howard does not teach or suggest, as in amended claims 1, 22, and 24, methods for inducing the consumption of calcium-containing products or dairy for weight loss in an individual in need thereof based on promoting or communicating the benefits of calcium from the calcium containing products or dairy to directly induce weight loss, reduce weight gain, and/or increase the metabolic consumption of adipose tissue in the individual.

Instead, Howard is directed to methods of treating obesity comprising restricting the caloric intake of an obese individual to not more than 600 kcal per day by administering a supplement and skimmed milk which provide the individual with the minimum daily requirement of various minerals, vitamins, proteins, amino acids, carbohydrates, sufficient fat, oil and other sources of essential fatty acids (e.g., abstract, column 3, lines 37-46, and claims). Nowhere in Howard is it disclosed that calcium or dairy alone directly induces weight loss, reduces weight gain, and/or increases the metabolic consumption of adipose tissue in the individual, as opposed to indirectly causing a dieter to lose weight by reducing overall caloric intake.

The weight loss that may occur pursuant to Howard is due to the intake of very low calorie count, not for the effects of calcium or dairy in inducing weight loss. Simply, to supplement this very low intake of calories, Howard uses supplements and skimmed milk, which includes calcium, to provide the required nutritional intake of minerals and other essential ingredients. For example, Howard states:

As regards the minerals necessarily included in the diet, namely sodium, potassium and magnesium, these are all present to some extent in skimmed milk, but require to be supplemented to bring their

skimmed milk-levels up to human needs. As will be explained hereinafter, the supplement of this invention is capable of use in conjunction with a range of daily intakes of skimmed milk but is especially designed to be used within a range of from (a) 123g/day dried skimmed milk (equivalent to 400 Kcals), the so-called "maximum skimmed milk intake", down to (b) 61.3g dried skimmed milk (equivalent to 200 Kcals), the so-called "minimum skimmed milk intake." These designed limits are chosen because (a) represents the optimum quantity of reconstituted milk which a patient could reasonably be expected to consume, the 400 Kcals it contains are not excessive, and the size of supplement is reasonable in volume; while (b) represents approximately the minimum quantity of skimmed milk which is needed to supply the daily requirement of calcium, so that below this level it would be considered necessary to supplement with additional calcium, which would raise the weight of the supplement to an excessive amount for the patient to tolerate.

Column 4, lines 51-column 5, line 5. Here, Howard is directed to a diet low in calories and with a minimal amount of various minerals and other ingredients.

Furthermore, Howard teaches that:

Both calcium and phosphorus are also essential mineral elements in human nutrition, but dried skimmed milk contains substantial amounts of both these minerals. The milk-levels of calcium are sufficient, without any supplementation, over the whole range of daily skimmed milk-intake for which the supplement of this invention is designed. Consequently calcium never need be present in the supplement though of course its presence therein is not excluded.

Column 7, lines 13-21. Howard indicates that the daily amount of calcium obtained from the skimmed milk is about 800 mg (column 1, line 19 and line 66). However, nowhere in Howard is it taught or suggested that the calcium from the calcium containing products or dairy is directly inducing weight loss, reducing weight gain, and/or increasing the metabolic consumption of adipose tissue in the individual.

Moreover, Applicants contend that Tabbita does not disclose, teach or suggest any of the elements of independent claims 1, 22 and 24, nor cure the defects of Howard.

Tabbita discloses the promotion of milk for its beneficial effects on osteoporosis, not weight-related conditions, and the attempt of the dairy industry to market milk as being "cool", not as an agent producing weight-related benefits. Furthermore, Tabbita emphasizes the declining interest in the consumption of milk, attributing it to the perception that milk has a high fat content, and that when the fat content is removed, then the milk no longer contains beneficial vitamins and minerals, except for the calcium for osteoporosis. This statement would lead one away from the teaching of the present invention, which involves the use of dietary calcium or dairy, to directly induce weight loss or other weight-related effects.

Tabbita does not teach or suggest, as in amended claims 1, 22, and 24, methods for inducing the consumption of calcium-containing products or dairy for weight loss in an individual in need thereof based on promoting or communicating the benefits of calcium from the calcium containing products or dairy to directly induce weight loss, reduce weight gain, and/or increase the metabolic consumption of adipose tissue in the individual.

Therefore, Howard or Tabbita, either alone or in combination, do not disclose, teach or suggest the claimed invention as set forth in claims 1, 22, or 24. Nor do they teach or suggest the subject matter of dependent claims 2-3, 5-7, 9-20, 23 and 26-30, which include additional limitations distinguishing them from the cited references.

Applicants respectfully request that the rejection to claims 1-3, 5-7, 9-20, 22-24 and 26-30 be withdrawn.

The Examiner further rejects claim 8, as being obvious based on Howard and Tabbita, in further view of Bruno, which teaches the use of calcium to induce a metabolic change in an individual (see column 12, lines 5-10). However, Bruno does not teach, disclose or suggest that calcium is inducing a weight-related metabolic change, e.g., directly inducing weight loss, reducing weight gain, and/or increasing the metabolic consumption of adipose tissue in the individual. Instead, Bruno teaches weight control in humans and other animals using a diet with reduced calories, reduced or no fat, and a controlled amount of protein in combination with supplemental dietary amino acids to control appetite and modulate the effects of an altered metabolism during dieting (column 1, lines 11-16).

Therefore, Bruno, alone or in combination with other references, does not disclose, teach, suggest, or cure the defects of Howard or Tabbita, as discussed above for claim 1.

Applicants respectfully request that the rejection to claim 8 be withdrawn.

The Examiner further rejects claim 21, as being obvious based on Howard and Tabbita, in further view of Christiansen, which teaches a trademark calcium-fortified product. However, Christiansen refers in example 4 to a cereal containing a particular brand of calcium chelate, but does not describe communicating a trademark for a calcium-containing product for its weight-related effects as recited in the present claims. Christiansen does not disclose, teach, suggest, or cure the defects of Howard or Tabbita, as discussed above for claim 1.

Applicants respectfully request that the rejection to claim 21 be withdrawn.

Claims 1-3, 5-24 and 26-30 are patentable because none of the cited references or material disclose, teach or suggest the present invention. Applicants respectfully request these rejections be withdrawn.

### **Conclusion**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-3, 5-24 and 26-30 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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